

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

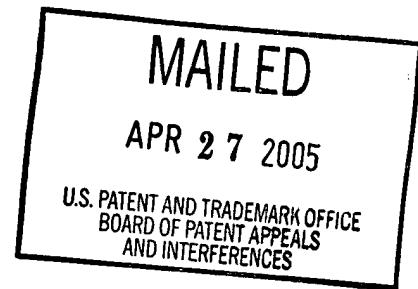
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ASHOK RAMPAL, RAJEEV S. RAGHUVANSHI and
MANOJ KUMAR

Appeal No. 2005-0732
Application No. 09/941,970

ON BRIEF



Before ELLIS, SCHEINER and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1, 2 and 5-12, which are all of the claims pending in this application.

Claim 1 is illustrative of the claims on appeal and reads as follows:

1. A controlled release formulation of erythromycin A or a derivative thereof, suitable for once daily administration, comprising erythromycin from about 66% w/w to about 90% w/w of the total tablet weight and from about 0.1% to about 4% w/w of one or more pharmaceutically acceptable rate controlling polymers.

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The prior art references cited by the examiner are:

Fuisz et al. (Fuisz)	5,518,730	May 21, 1996
Ayer et al. (Ayer)	6,096,339	Aug. 1, 2000
Misra et al. (Misra)	5,869,098	Feb. 9, 1999
Talwar et al. (Talwar)	WO 00/15198	Mar. 23, 2000

Grounds of Rejection

Claims 1, 2 and 5-12 stand rejected under 35 U.S.C. 103(a), as obvious over Talwar in view of Fuisz, Ayer and Misra.

We affirm this rejection.

Claim Grouping

According to appellants, all of the claims stand or fall together. Brief, page 2. Therefore, we select claim 1 as representative of the claims on appeal. 37 C.F.R. § 1.192(c)(7)(2004), now 37 C.F.R. § 41.37(c)(1)(vii) (September 13, 2004)

DISCUSSION

35 U.S.C. 103(a)

Claims 1, 2 and 5-12 stand rejected under 35 U.S.C. 103(a), as obvious over Talwar in view of Fuisz, Ayer and Misra.

It is the examiner's position that (Final Rejection, pages 2-3):

Talwar et al discloses [a] controlled release formulation comprising cellulosic polymers and antimicrobial/bacterial agents. Among the agents named are ciprofloxacin and clarithromycin, an erythromycin derivative, (pg. 14, para. 2). The active agent is present in most embodiments about

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70% w/w total weight of the tablet (examples). The formulation further comprises cellulosic polymers such as hydroxypropyl methylcellulose in concentrations from 0.5% to about 5% w/w total weight of the tablet (pg. 20, para. 4 – pg. 21, para. 1). The tablet further comprises xanthum gum (examples), sodium alginate (example 4), and Carbopol (example 1).

According to the examiner, what is lacking from Talwar is a working example of clarithromycin in the monolithic formulation. Final Rejection, page 3. The examiner notes that ciprofloxacin and erythromycin, along with its derivatives are well known antibiotics, and that substituting and interchanging these compounds is well within the level of ordinary skill in the art. Id. To support this position the examiner relies on Fuisz, Ayer and Misra. The examiner concludes that (Final Rejection, pages 3-4):

[a] skilled artisan would have been motivated to substitute the similar active agents of the reference[s] into the formulation of Talwar, using the method of Talwar, in order to impart antibiotic properties on the formulation. Talwar provides teachings that a monolithic dosage form is possible of antibiotics such as ciprofloxacin and erythromycin derivatives like clarithromycin. There would have been a reasonable level of expectation [of success] at the time of the invention, which would have resulted in a monolithic single dosage of clarithromycin.

We agree that the examiner has provided sufficient evidence to support a prima facie case of obviousness. Talwar reasonably appears to recite the claimed proportions of antibiotic and rate controlling polymer. In addition, the examiner has provided evidence (Fuisz, Ayer and Misra) that provides a sufficient reason, suggestion or motivation for the interchangeability of erythromycin A, its derivatives and related antibiotic compounds.

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Where the prior art, as here, gives reason or motivation to make the claimed invention, the burden then falls on an appellants to rebut that prima facie case. Such rebuttal or argument can consist of any other argument or presentation of evidence that is pertinent. In re Dillon, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991).

Appellants argue in rebuttal that Talwar "does not use the term 'rate controlling polymer' but nonetheless many of the polymers disclosed in Talwar function as rate controlling polymers." Brief, page 4. Appellants find that Talwar's examples illustrate the use of rate controlling polymers at between 8% and 50% w/w of the tablet. Brief, page 6. Thus, appellants argue that "none of the cited references taken separately or in combination describe or suggest rate controlling polymers making up from 0.1% w/w to about 4% w/w of the total tablet weight." Brief, page 7. Appellants particularly argue that the presence of xanthan gum, sodium alginate and PVP in Talwar Example 2 "together make up greater than 17% of the tablet weight." Brief, page 6.

During the examination of an application, claims are given the broadest reasonable interpretation. In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Here, we agree with the examiner that the recitation in claim 1 of "[a] controlled release formulation ... comprises ... from about 0.1% w/w to about 4% w/w of one or more pharmaceutical acceptable ...polymer" can reasonably be understood to mean that only one pharmaceutically acceptable polymer in a given formulation need be present in the concentrations listed. Answer, page 3.

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To that end, the examiner points to appellants' Example 1, Table 1.1, page 10, lines 1-5 of the specification (Answer, page 5). We find that the example shows a formulation which includes 1% w/w sodium alginate, 3% w/w of xanthan gum, and 10.1% w/w of polyvinylpyrrolidone (PVP), a swelling agent. This example is nearly identical to Table 3, Example 2 of Talwar (page 23, lines 1-27) which discloses 1.0% w/w of sodium alginate, 1.5% w/w of xanthan gum and 15% w/w of PVP, a swelling agent.

In addition, the examiner points to Talwar's disclosure of cellulosic polymers such as hydroxypropyl methylcellulose in concentrations from 0.5% to about 5% w/w total weight of the tablet (pg. 20, para. 4 – pg. 21, para. 1). Answer, page 3. Here, we agree with the examiner that Table 3 of Talwar (Example 2, page 23, lin. 1-27) describes a formulation where the xanthan gum and sodium alginate are well below 3%. Answer, pages 3-4.

Therefore, we are not persuaded by appellants' argument that Talwar does not disclose between about 0.1% w/w to about 4% w/w of rate controlling polymers, particularly in view of the fact that Talwar describes the PVP component of his formulation as a swelling agent, which is consistent with how PVP functions in appellants' formulation.

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Next, appellants take issue with the examiner's statement in the Answer that "substituting and interchanging these compounds is within the level of ordinary skill in the art." Appellants argue (Brief, page 7) that the

cited references fail to describe or suggest at what dosage strength the clarithromycin would be interchanged. The chemical arts is [sic, are] an unpredictable field and there is no basis upon which one can simply assert that one can interchange compounds, broadly classed as antibiotics, at the same level within a formulation. Each compound has unique physical properties, such as [a] dissolution profile, spatial bioavailability, and adsorption within the gastrointestinal tract. All of these properties affect the amount or concentration level necessary to impart the intended therapeutic effect of the formulation. As a consequence, Applicants submit there is no general rule that antibiotics can be substituted in formulations without regard to the formulation or the level of the antibiotic, as apparently asserted in the Office Action.

We acknowledge appellants' above argument, however, we note that appellants claim neither a specific dissolution profile, spatial bioavailability, a level of adsorption within the gastrointestinal tract or a dosage or concentration level of antibiotic. Instead, appellants chose to broadly claim an amount of antibiotic based on the w/w of the total tablet. Appellants admit in the specification and in claim 2, and the examiner has provided evidence to support the position, that clarithromycin is a derivative of erythromycin. Thus, one of ordinary skill in the art would understand that clarithromycin is likely to share similar properties with erythromycin. Moreover, appellant's arguments regarding differences in antibiotic dissolution profile, spatial bioavailability, level of adsorption within the gastrointestinal tract or a dosage or concentration level of antibiotic are unsupported by evidence. Appellants have not provided any evidence that one of ordinary skill in the art would not use clarithromycin or ciprofloxin in similar

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w/w amounts in a controlled release tablet. Appellants are reminded that arguments of counsel cannot take the place of evidence. In re DeBlauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984), In re Payne, 606 F.2d 303, 315, 203 USPQ 245, 256 (CCPA 1979).

Finally, appellants argue that the only disclosure in Fuisz that references an erythromycin derivative is Example 1, in which 200 mg of vancomycin is melt spun into a polymer product and makes up 11% of the product. "Thus, at most Fuisz would have motivated one of skill in the art to make a formulation that includes 11% clarithromycin rather than the claimed 66% to about 90% w/w." Brief, page 9.

In response, the examiner correctly notes that, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). Instead, the test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). See also, Answer, page 6. The examiner clearly relies on Talwar as evidence of the recited w/w portion of antibiotic in the formulation. Therefore, we are not persuaded by appellants' argument.

In view of the above, we do not find appellant has presented sufficient evidence or argument to rebut the examiner's prima facie case of obviousness.

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CONCLUSION

The rejection of claims 1, 2 and 5-12 under 35 U.S.C. 103(a), as obvious over Talwar in view of Fuisz, Ayer and Misra is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

 Ellis
JOAN ELLIS

Administrative Patent Judge

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APPEALS AND
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